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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,241	08/29/2001	Krishan Chari	82300D-W	9136

7590

03/16/2005

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,241

Applicant(s)

CHARI ET AL.

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 26-28, 30-34, 43-46, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 44-46, 48 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26-28, 30-34 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 December 2005 has been entered.

Status of the Claims

2. This action is in response to papers filed 14 December 2004 in which claims 1, 27, 44 and 49 were amended and claims 50-51 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 16 July 2004, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 1-24, 26-28, 30-34 and 43 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8, 13, 15-17, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al (U.S. Patent No. 5,714,340, issued 3 February 1998).

Regarding Claim 1, Sutton et al disclose a coating composition comprising microspheres (beads) dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling agent forms a gel (Column 3, lines 3-10; Column 6, line 55-Column 7, line 27; and Column 11, lines 53-57) wherein the gel is capable of immobilizing the microspheres at random positions on a substrate (Fig. 2-5 illustrate the "receptor beads" randomly positioned on the substrate, Column 9, line 32-Column 10, line 15). Sutton et al further disclose the microspheres are dispersed uniformly (Example 2, Column 14, lines 50-52).

Regarding Claim 2, Sutton et al disclose the support is not premarked and does not contain microwells (Column 9, lines 33-41 and Fig. 1-7).

Regarding Claim 3, Sutton et al disclose the composition wherein the pattern is maintained upon gelling (Column 7, lines 33-41 and Fig. 2-5).

Regarding Claim 4, Sutton et al disclose the composition wherein the microspheres are chemically functionalized to have surface active sites (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

Regarding Claim 5, Sutton et al disclose the composition wherein the active sites carry organic or inorganic attachments (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

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Regarding Claim 6, Sutton et al disclose the composition wherein the active site has organic or inorganic attachments thereon that are capable of chemical or physical interaction (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

Regarding Claim 7, Sutton et al disclose the composition wherein the active site is bioactive (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

Regarding Claim 8, Sutton et al disclose the composition wherein the bioactive site interacts with proteins or fragments thereof (Column 10, lines 15-39).

Regarding Claim 13, Sutton et al disclose the composition wherein the gelling agent undergoes thermal gelation (e.g. 37° C, Column 19, lines 10-28).

Regarding Claim 15, Sutton et al disclose the composition wherein the microspheres have a mean diameter of between 1 and 50 microns (Column 5, lines 11-32). It is noted that both the "bead spreading layer" and the "receptor layer" of Sutton et al meet the limitations of Claim 1.

Regarding Claim 16, Sutton et al disclose the composition wherein the microspheres have a mean diameter of between 3 and 30 microns (Column 5, lines 11-32).

Regarding Claim 17, Sutton et al disclose the composition wherein the microspheres have a mean diameter of between 5 and 20 microns (Column 5, lines 11-32).

Regarding Claim 21, Sutton et al disclose the composition wherein the microspheres comprise a synthetic or natural polymeric material (Column 5, lines 11-32).

Response to Arguments

5. Applicant asserts that in contrast to the instantly claimed single layer, the microspheres of Sutton et al form a stack comprising multiple layers of beads and aggregates of microspheres within the layers. Applicant asserts that the claimed invention is directed to microspheres immobilized in a random distribution and evenly dispersed with a uniform density. The argument has been considered but is not found persuasive because the above claims are drawn to a coating composition and microarray that comprise a single layer of

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microspheres dispersed in a fluid on a substrate, the fluid containing a coating aid and a gelling agent. The open claim language "comprising" encompasses compositions having multiple layers, because a multi-layered composition comprises a single layer, while it contains multiple-single layers, it does comprise a single layer. Therefore, the multiple layers of Sutton are encompassed by the claimed single layer. Furthermore, while Sutton illustrates aggregates, the claimed single layer is encompassed by the aggregates because the aggregate composition comprises a single layer.

Furthermore, the claims, as amended, encompasses a wide range of compositions. The composition components (i.e. microspheres, substrate, coating aid and gelling agent) are broadly claimed so as to encompass an enormous genus of each component because the claims do not clearly define or limit the components. There is no standard in the art regarding definitions of terms such as microsphere, substrate, coating air and gelling agent. Therefore, the terms are each broadly claims so as to encompass a large number of possible components. For example, the claimed composition encompasses cookie dough wherein the microspheres are sugar particles (or chocolate chips), the substrate is a cookie sheet, the coating aid is fat or butter and the gelling agent is eggs. Another example encompassed by the instant claims is cells plated in agarose, wherein the microspheres are cells, the substrate is the Petri dish, the coating aid is the buffer or media in which the agarose is melted and the gelling agent is agarose.

6. Claims 1-24 and 26-28, 30-34 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce et al (U.S. Patent No. 4,258,001, issued 24 March 1981).

Regarding Claim 1, Pierce et al disclose a coating composition comprising microspheres (beads) dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling

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agent forms a gel (Abstract and Column 16, line 55-Column 18, line 39) wherein the gel is capable of immobilizing the microspheres at random positions on a substrate (Fig. 2-14 illustrate randomly positioned beads on the substrate (Column 17 lines 1-67). Pierce et al further teach the microspheres are randomly dispersed with a uniform density i.e. stable dispersion (Column 17, lines 11-55).

Regarding Claim 2, Pierce et al disclose the support is not premarked and does not contain microwells (Column 24, line 65-Column 25, line 5 and Fig. 2-14).

Regarding Claim 3, Pierce et al disclose the composition wherein the pattern is maintained upon gelling (Column 19, lines 48-65).

Regarding Claim 4, Pierce et al disclose the composition wherein the microspheres are chemically functionalized to have surface active sites (Column 30, line 32-Column 31, line 44).

Regarding Claim 5, Pierce et al disclose the composition wherein the active sites carry organic or inorganic attachments (Column 30, line 32-Column 31, line 44).

Regarding Claim 6, Pierce et al disclose the composition wherein the active site has organic or inorganic attachments thereon that are capable of chemical or physical interaction (Column 30, line 32-Column 31, line 44).

Regarding Claim 7, Pierce et al disclose the composition wherein the active site is bioactive (Column 30, line 32-Column 31, line 44).

Regarding Claim 8, Pierce et al disclose the composition wherein the bioactive site interacts with proteins or fragments thereof (Column 30, line 32-Column 31, line 44).

Regarding Claim 9, Pierce et al disclose the composition wherein the microsphere contains a signature (Column 31, lines 9-19).

Regarding Claim 10, Pierce et al disclose the composition wherein the signature comprises an oil-soluble dye (Column 31, lines 9-19).

Regarding Claim 11, Pierce et al disclose the composition wherein the signature is interrogatable by optical means (Column 31, lines 9-19).

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Regarding Claim 12, Pierce et al disclose the composition wherein the gelling agent is gelatin i.e. the microspheres within the composition are coated with gelatin therefore the composition comprises a gelatin gelling agent (Column 30, lines 49-54).

Regarding Claim 13, Pierce et al disclose the composition wherein the gelling agent undergoes thermal gelation (Column 19, lines 48-65).

Regarding Claim 14, Pierce et al disclose the composition wherein the gelling agent is gelatin i.e. the microspheres within the composition are coated with gelatin therefore the composition comprises a gelatin gelling agent (Column 30, lines 49-54).

Regarding Claim 15, Pierce et al disclose the composition wherein the microspheres have a mean diameter of between 1 and 50 microns (Column 9, lines 35-64).

Regarding Claim 16, Pierce et al disclose the composition wherein the microspheres have a mean diameter of between 3 and 30 microns (Column 9, lines 35-64).

Regarding Claim 17, Pierce et al disclose the composition wherein the microspheres have a mean diameter of between 5 and 20 microns (Column 9, lines 35-64).

Regarding Claims 18-20, Pierce et al disclose the composition wherein the microsphere range in size from 1 to 200 microns (Column 9, lines 40-41). The instant claims are drawn to microspheres "capable of being" immobilized at concentrations 100-1 million/cm²; 1,000 to 200,00 / cm²; and 10,000 to 100,00/cm². While Pierce do not teach a density of immobilization, the 1 micron microspheres of Pierce are clearly capable of being immobilized at the claimed densities as claimed. Therefore, Pierce discloses the claimed microspheres.

Regarding Claim 21, Pierce et al disclose the composition wherein the microspheres comprise a synthetic or natural polymeric material (Table I, Column 13, lines 8-44).

Regarding Claim 22, Pierce et al disclose the composition wherein the polymeric material is amorphous i.e. polystyrene (Table I, Column 13, lines 8-44).

Regarding Claim 23, Pierce et al disclose the composition wherein the polymeric material is amorphous i.e. polystyrene (Table I, Column 13, lines 8-44).

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Regarding Claim 24, Pierce et al disclose the composition wherein at least one active site comprises a functionality as claimed (Column 10, line 56-Column 13, line 4).

Regarding Claim 26, Pierce et al disclose the composition wherein the microspheres are prepared by emulsion polymerization (Column 10, lines 42-65).

Regarding Claim 27, Pierce et al disclose a microarray comprising a substrate coated with a composition comprising microspheres (beads) dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling agent forms a gel (Column 8, lines 24-27 and Column 16, line 55-Column 18, line 39) wherein the gel is capable of immobilizing the microspheres at random positions on a substrate (Fig. 2-14 illustrate randomly positioned beads on the substrate (Column 17 lines 1-67). Pierce et al further teach the microspheres are randomly dispersed with a uniform density i.e. stable dispersion (Column 17, lines 11-55).

Regarding Claim 28, Pierce et al disclose the microarray wherein the substrate is free of receptors designed to physically or chemically interact with the microspheres (Column 24, line 65-Column 25, line 37) whereby the microspheres remain stably dispersed within the carrier i.e. not interacting with the support (Column 17, lines 1-21 and Column 18, lines 1-24).

Regarding Claim 30, Pierce et al disclose the microarray wherein the gelling agent is gelatin i.e. the microspheres within the composition are coated with gelatin therefore the composition comprises a gelatin gelling agent (Column 30, lines 49-54).

Regarding Claim 31, Pierce et al disclose the microarray wherein the microspheres bear chemically active sites (Column 10, line 56-Column 13, line 3 and Column 30, line 32-Column 31, line 44).

Regarding Claim 32, Pierce et al disclose the microarray wherein the active site is bioactive (Column 30, line 32-Column 31, line 44).

Regarding Claim 33, Pierce et al disclose the microarray wherein the substrate comprises glass, plastic, cellulose acetate (Column 24, line 65-Column 25, line 37).

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Regarding Claim 34, Pierce et al disclose the microarray wherein the substrate is flexible e.g. paper (Column 25, lines 1-3).

Regarding Claim 43, Pierce et al disclose the microarray wherein the support is not premarked and does not contain microwells (Column 24, line 65-Column 25, line 5 and Fig. 2-14).

Response to Arguments

7. Applicant argues that in contrast to the instantly claimed single layer, the microspheres of Pierce form a three-dimensional structure. The argument has been considered but is not found persuasive because the above claims are drawn to a coating composition and microarray that comprise a single layer of microspheres dispersed in a fluid on a substrate, the fluid containing a coating aid and a gelling agent. The open claim language "comprising" encompasses compositions having multiple layers, because a multi-layered composition comprises a single layer, while it contains multiple-single layers, it does comprise a single layer as claimed. Therefore, the multiple layers of Pierce are encompassed by the claimed single layer.

8. Claims 1-2, 4, 9-12, 15-17, 21-23, 26-28, 30-31, 33-34 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Chari et al (U.S. Patent No. 6,599,668, filed 3 August 2001).

Regarding Claim 1, Chari et al disclose a coating composition comprising a single layer of microspheres (Column 3, lines 57-60) randomly dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling agent (Column 5, line 55-Column 10 and Example 1, Column 12, lines 10-22 and Claim 19).

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Regarding Claim 2, Chari et al disclose the support is not premarked and does not contain microwells (Column 7, lines 8-20).

Regarding Claim 4, Chari et al disclose the composition wherein the microspheres are chemically functionalized to have surface active sites i.e. cross-linking agent (Column 6, lines 11-13).

Regarding Claim 9, Chari et al disclose the composition wherein the microsphere contains a signature i.e. color dye (Column 5, lines 24-54).

Regarding Claim 10, Chari et al disclose the composition wherein the signature comprises an oil-soluble dye (Column 5, lines 34-35).

Regarding Claim 11, Chari et al disclose the composition wherein the signature is interrogatable by optical means i.e. color dye (Column 5, lines 24-54).

Regarding Claim 12, Chari et al disclose the composition wherein the gelling agent is gelatin (Column 5, lines 60-65).

Regarding Claim 15, Chari et al disclose the composition wherein the microspheres have a mean diameter of between 1 and 50 microns (Column 12, lines 15-17).

Regarding Claim 16, Chari et al disclose the composition wherein the microspheres have a mean diameter of between 3 and 30 microns (Column 12, lines 15-17).

Regarding Claim 17, Chari et al disclose the composition wherein the microspheres have a mean diameter of between 5 and 20 microns (Column 12, lines 15-17).

Regarding Claim 21, Chari et al disclose the composition wherein the microspheres comprise a synthetic or natural polymeric material (Column 5, lines 24-30).

Regarding Claim 22, Chari et al disclose the composition wherein the polymeric material is amorphous i.e. polystyrene (Column 5, lines 24-28).

Regarding Claim 23, Chari et al disclose the composition wherein the polymeric material is amorphous i.e. polystyrene (Column 5, lines 24-28).

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Regarding Claim 26, Chari et al disclose the composition wherein the microspheres are prepared by emulsion polymerization or limited coalescence (Column 3, lines 57-67).

Regarding Claim 27, Chari et al disclose a microarray composition comprising a single layer of microspheres (Column 3, lines 57-60) randomly dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling agent (Column 5, line 55-Column 10 and Example 1, Column 12, lines 10-22 and Claim 19).

Regarding Claim 28, Chari et al disclose the microarray wherein the support is not premarked and does not contain microwells (Column 7, lines 8-20).

Regarding Claim 30, Chari et al disclose the microarray wherein the gelling agent is gelatin (Column 5, lines 60-65).

Regarding Claim 31, Chari et al disclose the microarray wherein the microspheres bear chemically active sites i.e. cross-linking agent (Column 6, lines 11-13).

Regarding Claim 33, Chari et al disclose the microarrays wherein the substrate comprises plastic, cellulose acetate or polyethyleneterephthalate (Column 6, line 61-Column 7, line 2).

Regarding Claim 34, Chari et al disclose the microarrays wherein the substrate is flexible (Column 6, line 61-Column 7, line 2).

Regarding Claim 43, Chari et al disclose the microarray wherein the support is not premarked and does not contain microwells (Column 7, lines 8-20).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-2, 4, 9-12, 15-17, 21-23, 26-28, 30-31, 33-34 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 15-16 and 19 of U.S. Patent No. 6,599,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are drawn to a method of making an array comprising a random distribution of microspheres, a coating aid and gelling agent and the instant claims are drawn to a composition comprising the patent random distribution of microspheres, a coating aid and gelling. As such, the patent process requires the instantly claimed composition. Therefore, the conflicting claims are not patentably distinct.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR


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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 14, 2005